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09/620,331	- 07/20/2000	Kimberly R. Gamble	ML-02C	2749

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Kenneth S Watkins Jr
372 River Drive
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EXAMINER

QUAN, ELIZABETH S

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/620,331	Applicant(s) GAMBLE ET AL.	
	Examiner Elizabeth Quan	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-27 and 29-32 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-27 and 29-32 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/20/2000 & 1/27/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the processing element disposed between the reduced diameter portion and the bottom-extraction opening must be shown or the feature(s) canceled from the claim(s). In the current drawings the processing element appears to surround the reduced diameter portion. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 10 is objected to because of the following informalities: In line 5 "device" should be "element". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 13, 22-25, 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 13 is rendered indefinite since the processing element does not appear to be disposed between the reduced diameter portion and bottom-extraction opening in the drawings.

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6. Claims 13 and 22-25 are rendered indefinite since there is also a lack of essential elements, such as aperture (215) in order for the liquid to be able to pass through the processing element.

7. Claim 31 is rendered indefinite since it recites that the device has a first septum seal and a second septum seal in a bottom portion of the device. The specification and drawings support a first septum seal in an upper portion of the device and a second septum seal in a bottom portion of the device. However, the septum seals are not both in the bottom portion of the device. It is suggested that "a/the septum seal" in claims 21, 26, 27, and 29 be labeled as "a/the first septum seal" and claim 31 be amended to "The method of claim 21 wherein the device further comprises [a first septum seal and] a second seal in [a] the bottom [portion] end of the device and comprising the additional step of inserting the sample deposit/extraction element through the second septum seal after inserting [a] the penetrating sample deposit/extraction element through the first septum seal, the conical guide, and into the reduced-diameter portion.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 10, 11, 19-21, 26, 27, 29, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,479,298 to Miller et al.

Miller et al. disclose a method of testing samples (abstract). A volume-adjusting insert (170), which comprises a top and bottom defining an axial direction, septum seal (172) in the upper portion, reduced-diameter portion having a close fit with an outside diameter of a penetrating sample deposit/extraction element and communicating with a bottom end of the insert between the septum seal and the bottom end of the insert, conical guide disposed between the septum seal and reduced diameter portion, and seal surface (191) on the outer surface of the insert for sealing an inside seal surface of a sample vessel (130), is inserted into the sample vessel (figs. 7-13; col. 2, lines 47-54, 58, and 59; col. 3, lines 1-4). The positioning and process of insertion the insert into the vessel is accomplished with the sample deposit/extraction element through frictional engagement of the sample deposit/extraction element and septum seal (fig. 9). The seal surface, reduced diameter portion, and a bottom portion of the vessel define a reduced-

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volume sample chamber compared to the volume of the sample vessel (figs. 7-13). A penetrating sample deposit/extraction element is positioned above the septum seal of the insert and inserted through the septum seal and conical guide to provide axial alignment of the insert and the sample deposit/extraction element (fig. 9). A sample fluid is transferred among the sample deposit/extraction element and reduced-volume sample chamber, which is defined by the bottom portion of the vessel (fig. 9).

Miller et al. do not explicitly disclose that the penetrating sample deposit/extraction element is inserted into the reduced-diameter portion. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Miller et al. to insert the penetrating sample deposit/extraction element beyond the conical guide into the reduced-diameter portion to facilitate quicker transfer of liquid into the reduced-volume sample chamber.

Miller et al. do not explicitly disclose performing the steps of positioning and inserting the penetrating sample deposit/extraction element into the insert before the steps of positioning and inserting the insert into the sample vessel such that the sample deposit/extraction element is required to position and insert the insert into the vessel. Applicant has not disclose that positioning and inserting the penetrating sample deposit/extraction element into the insert before positioning and inserting a volume-adjusting insert into the sample vessel solves any stated problem or is for any particular purpose. Moreover, it appears that the method would yield the same results no matter what the order of step is performed. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Miller et al. to insert the penetrating sample deposit/extraction element into the insert

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prior to position and inserting the insert into the sample vessel since it has been held that a reversal of method steps involves only routine skill in the art (*In re Einstein*, 8 USPQ 167).

Miller et al. do not explicitly disclose performing the step of withdrawing the insert from the vessel and positioning the insert to another processing location, such as another vessel, by frictional engagement of the sample deposit/extraction element and the septum seal. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Miller et al. to perform the claimed method steps in order to remove the insert after completing the fluid transfer in a manner without hazard or contamination to the operator and decontaminate the insert in a vessel and reuse it with other vessels.

12. Claims 21, 26, 27, 29, 30 and rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,169,602 to Pang et al.

Pang et al. disclose a method of testing samples (abstract). A volume-adjusting insert (10), which comprises a top and bottom defining an axial direction, septum seal (21) in the upper portion, reduced-diameter portion having a close fit with an outside diameter of a penetrating sample deposit/extraction element (11) and communicating with a bottom end of the insert between the septum seal and the bottom end of the insert, and conical guide disposed between the septum seal and reduced diameter portion, is inserted into the sample vessel (figs. 1-9). The positioning and process of insertion the insert into the vessel is accomplished with the sample deposit/extraction element through frictional engagement of the sample deposit/extraction element and septum seal (figs. 1-9). A penetrating sample deposit/extraction element is positioned above the septum seal of the insert and inserted through the septum seal and conical guide to provide axial alignment of the insert and the sample deposit/extraction element (figs. 1-

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9). A sample fluid is transferred between the sample deposit/extraction element and the vessel (figs. 1-9).

Pang et al. do not explicitly disclose performing the steps of positioning and inserting the penetrating sample deposit/extraction element into the insert before the steps of positioning and inserting the insert into the sample vessel such that the sample deposit/extraction element is required to position and insert the insert into the vessel. Applicant has not disclose that positioning and inserting the penetrating sample deposit/extraction element into the insert before positioning and inserting a volume-adjusting insert into the sample vessel solves any stated problem or is for any particular purpose. Moreover, it appears that the method would yield the same results no matter what the order of step is performed. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Pang et al. to insert the penetrating sample deposit/extraction element into the insert prior to position and inserting the insert into the sample vessel since it has been held that a reversal of method steps involves only routine skill in the art (*In re Einstein*, 8 USPQ 167).

Pang et al. do not explicitly disclose performing the step of withdrawing the insert from the vessel and positioning the insert to another processing location, such as another vessel, by frictional engagement of the sample deposit/extraction element and the septum seal. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Pang et al. to perform the claimed method steps in order to remove the insert after completing the fluid transfer in a manner without hazard or contamination to the operator and decontaminate the insert in a vessel and reuse it with other vessels.

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13. Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,169,602 to Pang et al. in view of U.S. Patent No. 5,945,070 to Kath et al.

Pang et al. do not explicitly disclose a processing element disposed at the bottom of the device and fluid transferred through the processing element. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a processing element, such as a filter, absorbent, or adsorbent, at the bottom of the device and transfer fluid through the processing element to remove particulate matter and other undesired contaminants from the fluid since it is very well known. Kath et al. is one of many references that teach the use of a processing element to filter fluid during transfer.

14. Claims 11, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,479,298 to Miller et al. in view of U.S. Patent No. 6,251,343 to Dubrow et al.

Miller et al. do not explicitly disclose performing the steps of positioning and inserting the penetrating sample deposit/extraction element into the insert before the steps of positioning and inserting the insert into the sample vessel such that the sample deposit/extraction element is required to position and insert the insert into the vessel. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made modify the method of Miller et al. to insert the penetrating sample deposit/extraction element into the insert prior to position and inserting the insert into the sample vessel to effectively seal the opening of the vessel with the insert and facilitate transfer of fluid within the vessel without contamination as taught by Dubrow et al. (col. 11, line 39-col. 12, line 27).

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15. Claims 12, 17, 18, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,479,298 to Miller et al. or U.S. Patent No. 5,169,602 to Pang et al. in view of U.S. Patent No. 6,083, 761 to Kedar et al. and/or U.S. Patent No. 4,787,971 to Donald.

Miller et al. disclose using hydraulic pressure generated by the penetrating sample deposit/extraction device to transport the sample fluid through the insert (figs. 7-13). Furthermore, the sample fluid is passed through a processing element (24) (see FIGS. 4-7; COL. 17-38). Miller et al. do not disclose a sample well with a bottom-extraction opening. However, multi-well plates with wells having a hole at the bottom are well known accessory equipment for solid phase extraction and draining of wastes as provided in Kedar et al. and Donald. Kedar et al. disclose a capillary hole (34) at the bottom of (28) of each well (28) of the plate (12) (see ABSTRACT; FIGS. 3-10; COL. 8, lines 51-42; COL. 13, lines 6-67; COL. 14, lines 1-48). The capillary hole (34) allows retains the smallest articles that the practitioner desires to remain in the well (28) while draining reagents, washing fluids, waste fluids and the like quickly such that the other fluids may be applied, making the system more conducive to quick assay protocols (see COL. 9, lines 35-37; COL. 14, lines 20-25). Donald discloses an opening (21) for draining the eluate from the vessel (10) (see FIGS. 1, 2, 6, and 7; COL. 3, lines 44-49; COL. 4, lines 5-9). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the sample vessel of Miller et al. with the bottom extraction hole to drain wastes from the insert as taught by Kedar et al. and Donald.

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Allowable Subject Matter

16. Claims 13, 31 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.


Response to Arguments

17. Applicant's arguments with respect to claims 10-27 and 29-32 have been considered but are moot in view of the new ground(s) of rejection. Art rejections based on U.S. Patent No. 5,567,309 to Classon et al. has been withdrawn since the reduced-diameter portion does not appear to have a close fit with an outside diameter of a penetrating sample deposit/extraction element.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (571) 272-1261. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth Quan
Examiner
Art Unit 1743

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